









## Autologous Ear Reconstruction: Towards a Semiautomatic CAD-based Procedure for 3D Printable Surgical Guides

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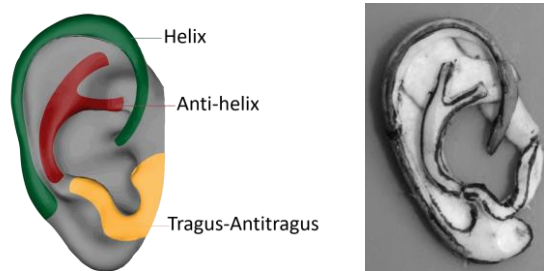
**Abstract.** The autologous ear reconstruction surgery, i.e. the reconstruction of the missing ear anatomy with autologous cartilage tissue in case of partial or complete absence of the auricular region, can be extremely complicated due to the unique shape and size of this anatomical region. Operations of sculpting and carving of the costal cartilage in order to realize the ear reproduction require a high degree of manual expertise and experience from the surgeon. The development of surgical aids that can provide the physician with guidelines during the reconstruction is being studied in the literature. However, state-of-the-art techniques do not represent the optimal solution and only partially help in the reconstruction process. They are based on two- or three-dimensional templates of the target anatomy, providing visual support, yet not helping in the actual reconstruction phase, or, in some cases, by providing active aid but not simplifying the procedure sufficiently. In this context, the option of creating custom cutting guides that could actively assist the surgeon both in the pre-operative planning phase and during the surgery was considered. The proposed approach involves the use of surgical guides adopted for the cutting and reconstruction of the individual anatomical elements involved. Through an iterative process carried out in collaboration with the surgeon the characteristics of the surgical guides have been defined. Subsequently, a method that can be applied systematically to model the cutting guides, ready to be printed with additive production techniques was defined. The procedure was designed with a view to a future semi-automatization of the entire process that could make the physician autonomous in the realization of the patient-specific guides.

**Keywords:** CAD modelling, Reverse Engineering, 3D Ear Templates, Autologous Ear Reconstruction, Personalized Medicine

**DOI:** <https://doi.org/10.14733/cadaps.2021.357-367>

## 1 INTRODUCTION

External ear reconstruction with autologous costal cartilage is a demanding surgery to restore the deformed or missing ear anatomy following a trauma, tumor intervention, or due to a congenital malformation (microtia) [12]. Among the techniques used in clinical practice to restore the ear anatomy, the Autologous Ear Reconstruction (AER) represents the preferred clinical treatment as it is a definitive solution with high degree of integration [15]. The AER surgical intervention makes use of autologous costal cartilages to reconstruct the missing anatomy and consists of the following surgical phases [5]: i) the harvesting of a portion of costal cartilage from the patient, ii) the manual cut and carve from costal cartilages of the principal ear anatomical elements and the suture of these components to create the ear "framework" (an example is shown in Figure 1(b)) and, iii) the positioning of the framework inside a skin pocket located in the auricular region. Assuming a complete reconstruction of the ear (in case the patient presents a total absence, i.e. anotia), the auricular elements involved are helix, anti-helix, tragus-antitragus (Figure 1(a)) and a base that provides a support on which the other elements are sutured together (Figure 1(b)) [6],[13],[16]. These anatomical parts allow to recreate the characteristic shape of the outer ear. The so generated cartilage framework aims to replicate the anatomy of the patient's healthy ear mirrored to resemble the missing ear, herein addressed as reference ear. In fact, the use of the mirrored healthy ear of the patient is fundamental to obtain a final aesthetic result appropriate to the patient's physiognomy.



**Figure 1:** (a) An indication of the auricular elements, (b) example of an ear framework [14].

The creation of a suitable framework is a tricky procedure due to the complex and extremely unique geometry to be reproduced [5] and requires practice and experience [11].

To assist the surgeon in the realization of the ear framework, the common practice involves the adoption of a 2D template. The 2D template is delivered by placing a 2D X-ray film over the healthy ear and tracing the contours. This approach presents some drawbacks: the resulting template is affected by significant errors due to the method used to create it (for example, the pressure exerted on the ear to track the contours changes the shape). Moreover, the 2D template does not provide enough information such as thickness and depth characteristics of the anatomical elements of the ear structure.

For these reasons, a 3D replica of the healthy ear were exploited as a reference during the reconstruction surgery [9],[18-19]. Nevertheless, according to state-of-the-art techniques, the 3D model is only a visual aid for the plastic surgeon rather than an actual physical template that can be used to identify and cut from the cartilage the individual segments involved in the reconstruction process. Therefore, the result is still strongly dependent on the surgeon artistic and technical skills and on the visual capacity to mentally draw out from the full model each anatomical element to be replicated. Faithful replicas of each individual element were also used to help

surgeon in the framework creation [7],[17], however this approach can be challenging due the complexity of the geometries to be replicated.

To overcome these limitations, this work focuses on devising a novel approach to create simplified (therefore more effectively helpful) patient-specific surgical guides that can help the surgeon in both simulating the procedure before entering the surgical room and in performing a guided surgery [2],[7],[17]. The final design of the surgical guides is the result of a preliminary trial phase during which the surgeon manually tested different versions of the medical devices. Among the benefits deriving from this approach, the surgeon has the advantage of having the reference ear elements at hand, moreover he is actively guided "at a low level" in the construction of the framework thanks to the use of surgical guides of each element, which can be used in the operating room to physically guide the tracing of contours on the harvested costal cartilage and its carving.

One of the long-term goals of this work is to have a fast, simple and easy-to-use system for the construction of the surgical guides, suitable for a hospital environment [3]. With this objective, this work has focused on the definition of effective and efficient surgical guides and the development of a systematic procedure that, starting from the 3D model of the reference ear [8] enables the 3D modeling of personalized guides. The procedure to date has not been automated, however this work, by defining a modelling method which can be applied systematically to any new case study, lays the foundations for a future automation of the process.

The devised procedure was validated on ten case studies, to test its robustness and repeatability. In order to define a standard method for the production of surgical aids, it was necessary to establish the medical requirements in first instance (Section 2). The method is presented in Section 3 and conclusion are drafted in Section 4.

## 2 DESIGN OF SURGICAL GUIDES

The delineation of technical and clinical requirements was the result of a multidisciplinary collaboration between clinicians and engineers; the latter have the role, *inter alia*, to identify the system requirements that can be the operational response to clinical needs.

The correct shape and functionality of the ear surgical guides (referenced also as "fragments" in the following) was identified through an iterative process of design and physical simulation during which the clinician tested the devised surgical guides in the realization of the ear framework [10]. Tests were performed by simulating the entire surgical procedure using anatomical physical replicas. Specifically, each simulation was performed using 1) a physical silicone replica of the rib cartilage obtained by mixing silicone rubber and other additives in order to make the cut as realistic as possible and 2) models of the surgical guides printed in PLA (Poly-Lactic Acid) through FDM 3D printing technology (MakerBot Replicator 2 [1]).

Initially, according to clinician's suggestions and state-of-the-art techniques, the guides of each anatomical element (helix, anti-helix, tragus-antitragus, depicted in Figure 1(a)) were created following faithfully the original anatomy, i.e. extracting them directly from the reference ear (Figure 2(a)). Details on acquisition modalities of the 3D geometry of the healthy ear with reverse engineering technologies are available in [8] and are not subject of interest of this work.

Simulations showed that the use of guides resembling faithfully the ear anatomical elements implies a few drawbacks: an excessive difficulty in the framework creation due to the complexity of the geometries that prevents an easy, precise and fast surgery. In addition, the reference 3D model acquired by means of optical scanning includes a layer of skin covering the auricular cartilage; for this reason, the actual auricular cartilage geometry is slightly modified (e.g. smoothed by the skin) when extrapolated from the model.

In light of these considerations, the shape of the surgical guides was defined as a simplification of each anatomical element's geometry. The simplification process consists in the enhancement of some fundamental edges and curves; in other words, the simplification of the element is achieved

by sampling the anatomy in crucial points in such a way as to maintain characterizing properties of the patient-specific anatomy and at the same time simplifying it by eliminating unnecessary features that may hinder the simplicity of the procedure.



**Figure 2:** Example of a surgical guides faithfully following the original anatomy: (a) complete model, (b) helix, anti-helix, tragus-antitragus, (c) base, (d) surgical guides superimposed to ear reference mesh.

As can be seen in Figure 3, through this process, simplified and caricatured shapes are obtained that fit the patient's anatomy yet removing details that are particularly difficult to reconstruct. This allows to obtain the desired aesthetic result during the surgical phase as the distinguishing features of the outer ear are reproduced and emphasized in view of the subsequent application of the skin layer. Figure 3 shows an example of the final guides' CAD models; specifically Figure 3(a) represents the complete framework, Figure 3(b) contains the helix (fragment#2), the anti-helix (fragment#3) and tragus-antitragus (fragment#4), Figure 3(c) represents the base, called fragment#1.



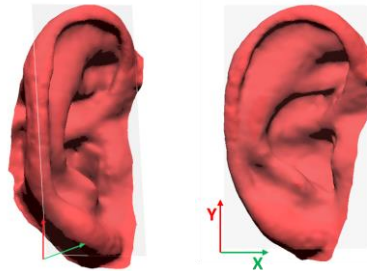
**Figure 3:** Example of a surgical guides created by simplifying the original anatomy: (a) all surgical guides, (b) helix, anti-helix tragus-antitragus, (c) base, (d) surgical guides superimposed to ear reference mesh.

As motivated above, specific ear features are emphasized in order to create surgical guides that can facilitate the extraction of the geometries from the cartilage tissue and thus simplify the manual cutting of each fragment. The definition of the characteristics that each anatomical surgical guide must have is obtained as a trade-off between the feasibility of the carving procedure, an aesthetically pleasant outcome and finally, as shown in Figure 3(d), the fitting of the overall sizes, volumes and primary shapes of the patient-specific anatomy. As can be seen from Figure 3, the surgical guides are built on the basis of the characteristics of the patient's ear anatomy, however they represent a simplification. This does not constitute a limit since it was experimentally validated by the surgeon during the iterative process of simulation, that the freehand reconstruction leads to an outcome that is further distant from the actual anatomy as well as being more complex procedure.

### 3 METHOD

To lay the foundations for implementing a semiautomatic procedure capable of creating the 3D models described above, this paper defines a simple, robust and repeatable procedure. Such a procedure is based on the identification of *key reference points* detectable on any auricular geometry, which can be used for the design of the surgical guides models. Through an iterative process, the surgical guides were created by CAD modelers and tested by surgeons so it was possible to identify the optimal number of *key reference points*. The objective was to obtain a simplification of the anatomy, validated by the surgeon, as result of the trade-off between the level of the simplification and the accuracy of the ear reconstruction.

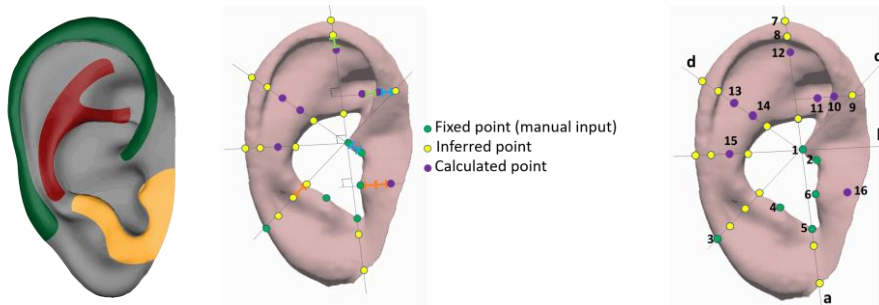
The developed procedure requires as input the pre-oriented mesh of the isolated ear, on which the fragments are modelled. Specifically, the pre-orientation can be achieved by looking for the plane on which the maximum area of the ear silhouette is projected. The definition of this orientation plane is a key step as the fragments are extracted from the 2D projection of the ear on this plane (in other words, the devised CAD modelling procedure, and therefore the identification of the *key reference points*, is based entirely on this plane). Additional studies are needed to automate the process which is to date designed to be a systematic procedure suitable for any anatomy and which will be integrated in a tool easily and autonomously usable by hospital staff, thus allowing the modelling of surgical templates directly on site.



**Figure 4:** Example of an (a) incorrect and (b) correct orientation of the reference ear.

The *key reference points*, shown in Figure 5(b)(c), are divided into *fixed* (identified thanks to a manual input), *inferred* and *calculated points*. Three *fixed points* (1,2,3 in Figure 5(c)) are placed on the helix in correspondence of the extremities of the element; other three *fixed points* (4,5,6 in Figure 5(c)) are located on the tragus-antitragus element. *Point 5* is located on the anatomical area of separation between tragus and antitragus; *points 4* and *6* are located in correspondence of the change of curvature of antitragus and tragus. By using *fixed points* it is possible to define four *lines* (Figure 5(b)): two *lines*, *a* and *c*, are identified as passing through respectively *points 1-5* and *1-3*; *line b* is perpendicular to *line a*, while *line d* is bisector of the angle defined between *line a* and *line b*. The *inferred points* are defined as belonging to these *lines* in correspondence with the boundaries of the anatomical elements extracted from the projection of the auricular anatomical elements on the plane. *Key points 7* and *8* are located at the intersection points of *line a* and the boundaries of the helix (see Figure 5(c)), analogously, *key point 9* on *line c*. Finally, *calculated points* derive from both *fixed* and *inferred points* according to anthropometric considerations and clinical requirements indicated by the physician. Specifically, *point 10* is positioned at a distance from *point 9* equal to the distance between *points 1* and *2*, along the direction defined by *line b*. *Point 12* is defined as belonging to *line a* at a distance from *point 8* equal to 20% of the segment defined by *point 1* and *8*. The same shift (parallel to *line b*) is applied to *point 10* to obtain *point 11*. The positioning of *points 13* and *14* depends on the two *inferred points* surrounding them on *line d*: in particular they are placed such to divide the segment delimited by the two *inferred points* into three equal parts. *Point 15* is located on *line b* midway between the two *inferred points*

surrounding it. Finally, *point 16* lies on a *line* perpendicular to the *line a* and passing through *point 6* at a distance from the latter calculated on the basis of the size of the tragus. The proportions derived from the green, blue and orange segments in Figure 5(b) are the result of medical guidelines and anthropometric considerations. Specifically, the green segment is used to maintain the right shape between helix and anti-helix, the blue segment to have a proportion along the development of the helix and finally the orange segment was chosen, in collaboration with the surgeon, proportional to the size of the tragus. All these considerations are visible and distinguishable in Figure 5. In Table 1 the reconstruction steps to obtain the CAD models realized with Geomagic Design X are shown and described in depth [20]. The average time to select the key reference points and complete the 3D modelling of the surgical guides was estimated to be around 40 minutes according to CAD's modeler experience.



**Figure 5:** Example of: (a) ear anatomical elements, (b) the extraction of the *key points* used for the CAD procedure, (c) labelled *key points* and *lines*.

	<p>To create fragment#1 two spline, <i>spline#1</i> and <i>spline#2</i>, are created and their extremities are joined together with a segment. <i>spline#1</i> is obtained connecting the points of Fig. 4(b) placed on the external perimeter of the helix. In the same way, <i>spline#2</i> is derived from the points defining the internal profile of the helix. The so generated profile is extruded of a fixed value (5 mm) defined with the clinicians according to a morphological study. A chamfer operation is then executed from the second-to-last to the last points of the two extremities with a final thickness of 2 mm. All edges are blended of 1 mm; the blending value, as well as the chamfer, were chosen experimentally to avoid the occurrence of errors.</p>
	<p>Fragment#2 is created from <i>spline#3#4#5#6</i>. Specifically, <i>spline#3</i> is created with the <i>key points</i> on the outer perimeter of the anti-helix and <i>spline#4</i> on the inner perimeter. These two splines are connected at the inferior side with a segment; <i>spline#5</i> connects the superior side. To create <i>spline#6</i>, two points (<i>auxiliary#1#2</i>) are extracted on <i>spline#5</i> at fixed distance from the two extreme points. This distance was set to 25% of the total length to ensure the Y-shape. The so generated profile is extruded with a fixed value (3 mm) defined according to morphological studies. The two upper extremities are chamfered from the minimum point of the Y-shape to the final thickness of 2 mm and the element's edges are successively blended of 1 mm. Again, the fillet and chamfer values were chosen experimentally to avoid the occurrence of errors.</p>

	<p>Fragment#3 is created from <i>spline#7</i> which is obtained from the points delimiting the tragus-antitragus region and closed with a segment at the antitragus extremity. The so generated profile is extruded with a fixed value (3 mm) defined according to morphological studies. The solid is then divided along <i>segment#1</i>, using the two <i>key points</i> on <i>line a</i>, in order to apply a chamfer operation to obtain a saddle point which characterises this auricular region. It is important to note that it is necessary to use the midpoint (<i>auxiliary#3</i>) between the two green points of the tragus to define the chamfer of this element. Again, the fillet and chamfer values were chosen experimentally, respectively of 1 mm and 2 mm, to avoid the occurrence of errors.</p>
	<p>Fragment#4 is created from <i>spline#10</i> which is obtained from the points on the outer perimeter removing the region between helix and tragus delimited by the <i>key points</i> in this area. To create <i>spline#10</i> an auxiliary point (minimum point along Y-axis, see Figure 4) is used to maintain the original curve of the lobe. <i>spline#8</i> is created from internal <i>key points</i> of the helix and outer <i>key points</i> of anti-helix. <i>spline#9</i> is created combining <i>spline#6</i> and <i>spline#5</i>. Two sockets are created through a cut extrusion of a value equal to 2 mm of the so generated profiles. A circular cut of 2 mm is made in the area of the lobe, as shown on the left <i>circle#1</i> is calculated as the circumference passing through <i>inferred</i> and <i>auxiliary points</i> in that area. The value of the cut extrusion was defined with the surgeon. The edge is then blended of 1 mm, again to avoid the occurrence of errors.</p>

**Table 1:** Evolution phases of an applying example of the devised procedure.

In conclusion, the procedure described requires the physician to identify the *fixed points*, then the process can be performed and finalised independently by a CAD modeler after a simple training on the ear anatomy.

## 4 RESULTS

It was deemed appropriate to test the method in terms of robustness and repeatability to ensure the quality and the compliance with medical requirements of the surgical guides.

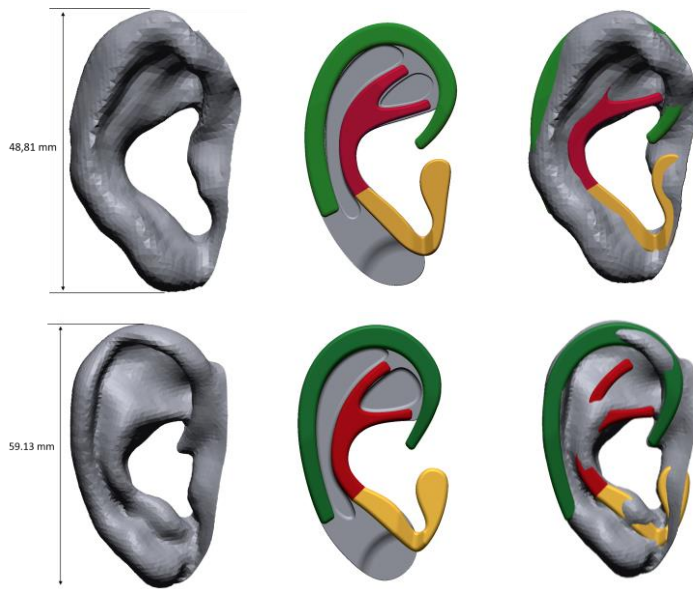
In order to evaluate the quality of the result, three specific parameters of the surgical guides were identified, in agreement with the surgeon: 1) the adaptation to the specific anatomy, 2) the usability during surgery and 3) the enhancement of the features in compliance with the medical requirements. The first requirement is to provide personalized surgical guides so that the final aesthetic result is consistent with the healthy ear and appropriate for the physiognomy of the patient. Secondly, usability evaluates the possible use, ensuring that the dimensions of the resulting elements are applicable to surgical practice. With this respect, it is difficult to handle and cut excessively small anatomical elements. Finally, the surgical guides must comply with medical guidelines described in Section 2, hence some ear features must be emphasized.

The composition of the test panel group has allowed the validation of the modelling process on significantly different external ear anatomies. Specifically, the sample is composed of ten subjects (5 women and 5 men, 6 right ears and 4 left ears). The study was carried out as a collaboration between the Meyer's Children Hospital (Italy) and Department of Industrial Engineering of Florence (Italy). Throughout the course of the research, patient data were anonymized before being included in the study in accordance with common health information practice. All methods were carried out in accordance with the guidelines laid down in the Declaration of Helsinki.

#### 4.1 Robustness

Within this context, robustness can be interpreted as the ability to cope with very different inputs which are due to the interindividual anatomical variability of the ear region [4]. The surgeon's evaluation is used as a metric to assess the outputs obtained by applying the proposed method. With this regard, all cases were determined compliant with the three above-mentioned parameters: 1) anatomical fitting, 2) simplification of the geometries and 3) caricature of the features.

By way of example, Figure 6 shows two key situations in which it is noticeable that the input ears' shape and size vary significantly and the proposed method is able to provide a valid result.



**Figure 6:** Two cases of the panel group with significantly different shape and size.

#### 4.2 Repeatability

Repeatability in this context indicates the closeness between the results of successive applications of the same methodology carried out under the same conditions. Since the procedure requires manual inputs it is essential to ensure that repeatability is not adversely affected by small variations of the *fixed points* which are manually inserted by the user. More specifically, intraobserver repeatability was expressed as the difference between the results obtained by one user applying the method twice on the same input and the interobserver repeatability was expressed as the difference between the results obtained by two different users on the same input. It should be mentioned that at this preliminary stage, no training was carried out to familiarize users with the method. The identification of anatomical points is therefore based on each physician background on the ear anatomy.

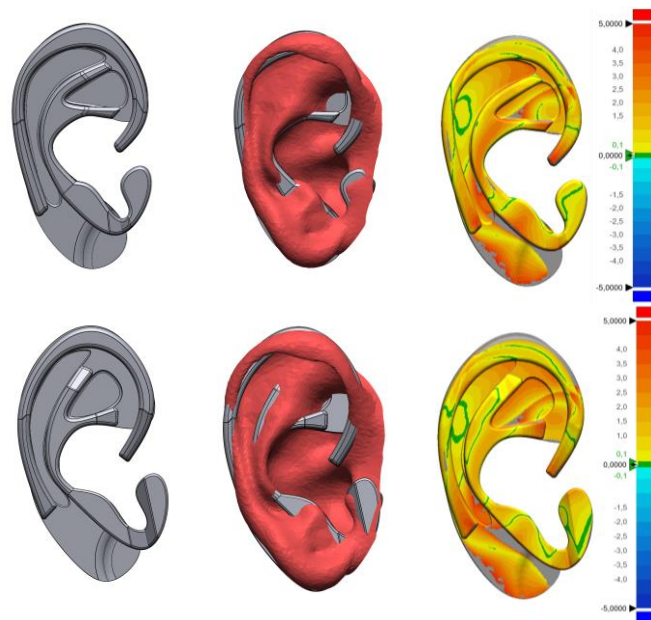
An example of the results of two successive iterations of the method based on two successive inputs of the same surgeon is shown in Figure 7.

Considering the absolute maximum of the deviation of 2 mm, the method is characterized by a good interindividual repeatability. An example of the results of two successive iterations of the method based on the inputs of two surgeon is shown in Figure 8.





**Figure 7:** Map deviation resulting from the comparison of two surgical guides obtained in two iteration with two successive inputs of the same surgeon.



**Figure 8:** Comparison of the models of surgical guides resulting from the procedure based on the inputs of two surgeons on the same anatomy and the relative deviation map between the surgical guide and the ear reference mesh.

The obtained results show that the method is subject to high intraindividual variability. For example, in Figure 8 it is observed that the surgical guides satisfy the parameters of 1) anatomical fitting (e.g. in both cases the helix characterizes the patient's anatomy), 2) simplification of the geometries and 3) caricature of the features. Fig. 8 also depicts the deviation map between the ear reference mesh and the obtained surgical guides: for both cases the max measured error is 4.9 mm and the mean deviation error is equal to  $1.61 \pm 1.31$  mm and  $1.64 \pm 1.27$  mm respectively, which are comparable. However, it should be noted that the surgical guides exhibit shape differences and therefore the criterion of intra-observer repeatability cannot be considered satisfied. This is due to the difficulty of identifying the same *fixed points* by two distinct surgeons.

## 5 CONCLUSIONS

In this article, the complexity of AER surgery is addressed. With a perspective of proposing solutions that actively guide the surgeon, personalized surgical guides were designed. The proposed surgical approach uses patient-specific surgical guides representing the anatomical elements involved in the reconstruction. In a first phase, thanks to a collaboration with Meyer's Children Hospital, the characteristics of the surgical guides were defined. On the basis of the medical requirements, a CAD procedure was systematized to model the surgical guides from the patient's anatomy. The procedure will be automated in future developments to make expert modellers and will be obtained directly in a hospital setting. Thus, the realization of the surgical guides will not require the intervention of expert modellers and will be obtained directly in a hospital setting.

The systematization of the method has been obtained by defining some *key reference points*, that can easily be identified on the ear, from which the surgical templates are constructed. The devised procedure was tested in the generation of ear surgical guides for ten people, five females and five males. The panel group structure has allowed the modeling method to be validated on significantly different ear geometries. The procedure was applied in each case according to the steps mentioned in Section 3. In each case the ear fragments were correctly generated without major complications. The generated CAD models were printed in PLA (Poly-Lactic Acid) through FDM 3D printing technology (MakerBot Replicator 2 [1]) and then evaluated and validated by the surgeon.

In this work it was not possible to compare the proposed method with other methods in literature since there are no state-of-the-art surgical guides that do not faithfully follow the anatomy, nor methods to achieve them.

The repeatability and robustness of the method were tested by evaluating the result according to three main parameters: fitting of the patient-specific ear, usability during surgery and caricatures of ear features. The tests showed that while the method proved to be robust to significant input variations, repeatability issues may arise. Specifically, the method is repeatable when used by the same surgeon, but with small variations in the manually inserted points, given the surgeons' personal view of the anatomy, the procedure can lead to significantly different results yet still hold its validity on all three criteria. As a consequence, although intraobserver repeatability is not achievable, using the proposed method, different users have the possibility to obtain effective surgical guides although slightly different according to the vision of each surgeon. Intraobserver repeatability could be satisfied with a training phase to align the surgeons on the identification of *fixed points* on different anatomies. Future developments foresee the automation of the modelling process starting from the proposed method and the realization of a user interface able to simplify the identification of *fixed points*.

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